

Remarks

Applicant appreciates the thorough examination of the present application as evidenced by the final Office Action mailed June 12, 2003 (Final Action). Claims 1-21 are pending in the present application. Claims 1-21 stand rejected under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 103. The concerns raised by the Examiner are addressed below.

I. Interview Summary

Applicant's representative, Shawna Cannon Lemon, appreciated the opportunity to speak with Examiner White on August 20, 2003 regarding the present application. During the discussion, Ms. Lemon noted that the Applicant could provide a Declaration of Naosuke Maruyama pursuant to 37 C.F.R. § 1.132 in response to the rejection under 35 U.S.C. § 103. The Examiner agreed to consider an Amendment After Final and the Declaration pursuant to 37 C.F.R. § 1.132 without the necessity of filing a Request for Continued Examination. Applicant appreciates the Examiner's willingness to consider this Amendment After Final and the Declaration of Naosuke Maruyama pursuant to 37 C.F.R. § 1.132 attached herewith.

II. Amendment to Claim 1

Applicant has amended claim 1 to recite as follows:

1. A dry direct tableting base material comprising low-substituted hydroxypropyl cellulose impregnated with a sugar or a sugar alcohol wherein the product resulting therefrom is dried, and wherein said low-substituted hydroxypropyl cellulose has a hydroxypropyl content in the range from 5 to 16% by weight.

This amendment further clarifies the subject matter of the invention and addresses the Examiner's issues as further discussed below. This claim amendment is supported by claim 1 as originally filed in addition to support found throughout the specification. Thus, Applicant respectfully submits that no new matter is presented, and respectfully requests entry of this claim amendment.

III. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. As suggested by the Examiner, Applicant has amended claim 1 to include the recitation "has a hydroxypropyl content in the range from 5 to 16% by weight." Accordingly, Applicant respectfully requests that this rejection be withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 103

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over PCT published application WO 98/53798 (Shimizu) and further in view of U.S. Patent No. 3,852,421 to Koyanagi et al. (Koyanagi et al.). Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Shimizu in view of Koyanagi et al., and further in view of U.S. Patent No. 6,380,381 to Obara (Obara). Applicant respectfully traverses these rejections.

Applicant agrees that "a difference in intended use cannot render a claimed composition novel." Final Action, page 3. Applicant also agrees that "[p]rocess limitations cannot impart patentability to a product that is not patentably distinguished over the prior art." Final Action, page 3. Applicant respectfully submits, however, that the claimed invention is indeed patentably distinguished over the cited references.

In responding to the obviousness rejection presented by the Final Action, Applicant directs the Examiner's attention to the use of the fluidized bed granulator in Shimizu as shown specifically in Working Example 6 and others. Employing a fluidized bed granulator enables the sugar alcohol to attach only to the surface of the low-substituted hydroxypropyl cellulose (L-HPC). In stark contrast, according to embodiments of the present invention, the L-HPC is impregnated with a sugar or sugar alcohol. Upon drying, the sugar or sugar alcohol exists inside the L-HPC. As a result, structurally different products are provided by the present invention than that presented by Shimizu. These structurally different products further provide improved properties that render the products useful for, among other things, dry direct tableting. Thus, in view of the structurally distinct products of the claimed invention, Applicant respectfully submits that claims 1-20 are not obvious in view of Shimizu.

Based upon the foregoing, Applicant does not believe that a *prima facie* case of obviousness has been established by the Final Action. As a precautionary measure, however, Applicant also submits herewith a Declaration Under 37 C.F.R. § 1.132 of Naosuke Maruyama. In general, the Declaration of Naosuke Maruyama presents the comparative data illustrating how the structural differences affect properties such as flowability index and disintegration time. Results of the comparative data show that the product provided by Shimizu has a lower flowability index as well as a longer disintegration time as compared to the base materials provided in Examples 1 through 4 of the present application.

In view of the arguments set forth, along with comparative data presented in the Declaration of Naosuke Maruyama, Applicant respectfully submits that one of ordinary skill in the art to which the present invention pertains would not rely upon the Shimizu reference proposing a mere combination of components yielding a solid pharmaceutical preparation, in order to arrive at the structurally distinct base materials of the present invention. The missing recitations are not supplied by Koyanagi et al. Koyanagi et al. merely proposes an excipient that comprises hydroxy alkyl cellulose or hydroxy alkyl alkyl cellulose for shaping medicaments into a solid body that can be disintegrated in the human body. *See* Abstract and column 1, lines 9-11. Koyanagi et al. does not teach or suggest a dry direct tableting base material comprising low-substituted hydroxypropyl cellulose impregnated with a sugar or a sugar alcohol wherein the product resulting therefrom is dried, and wherein said low-substituted hydroxypropyl cellulose has a hydroxypropyl content in the range from 5 to 16% by weight.

For the reasons set forth above, Applicant respectfully submits that claims 1-20 are not obvious in view of Shimizu alone or in combination with Koyanagi et al.

Applicant respectfully submits that claim 21 is not obvious in view of the combination of Shimizu, Koyanagi et al., and/or Obara. For reasons set forth above, Shimizu, alone or in combination with Koyanagi et al., does not render the present invention obvious. The missing recitations are not supplied by Obara which merely proposes a low-substituted hydroxypropyl cellulose that is distinct from the base materials of the present invention. Thus, conventional tableting formulation, as proposed by both Shimizu and Koyanagi et al., does not provide the improved product as recited in claim 1 and claims dependent therefrom, and Obara does not supply the missing recitations or motivation to arrive at the claimed

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invention. Consequently, Applicant respectfully submits that for the reasons discussed above, the base materials, as recited in claims 1 and 21, are patentably distinct from the product provided by Shimizu alone or in combination with Koyanagi et al. and/or Obara.

Accordingly, Applicant respectfully submits that claims 1-20 and claim 21 are patentable under 35 U.S.C. § 103(a), and respectfully requests that this rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



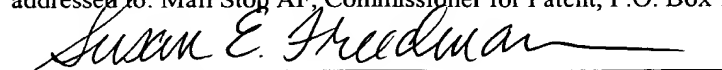
Shawna Cannon Lemon
Registration No. 53,888

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401

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Susan E. Freedman
Date of Signature: September 12, 2003